In re application of Farid Vaghefi et al.

Application No. 11/251,465

Filing Date: December 12, 2005

Attorney Docket No. P26238-A USA June 5, 2008

Page: 2

**Amendments to the Claims** 

1. (Original) An abuse-resistant controlled-release pharmaceutical composition, comprising

discrete particles of a pharmaceutically effective amount of an active compound capable of

abuse, wherein said discrete particles comprise surfaces that are wetted with a coating material

that is insoluble in water.

2. (Original) An abuse-resistant composition according to claim 1, wherein said particles are

distributed throughout a matrix comprising said coating material.

3. (Original) An abuse-resistant composition according to claim 2 wherein said particles are

water-soluble.

4. (Original) An abuse-resistant composition according to claim 3 wherein said matrix material is

non-erodable at pH less than about 6.

5. (Original) An abuse-resistant composition according to claim 4 wherein said matrix material is

erodable in the presence of bile salts and lipase.

6. (Original) An abuse-resistant composition according to claim 2 wherein said particles are

distributed throughout said matrix.

7. (Original) An abuse-resistant composition according to claim 1 wherein said compound is a

narcotic.

3. (Original) An abuse-resistant composition according to claim 3 wherein the application of

mechanical stress to said matrix increases the aqueous dissolution of active in said composition

by less than about 15% of said pharmaceutically effective amount in the first hour, and does not

substantially modify the dissolution rate of said composition thereafter.

Attorney Docket No. P26238-A USA

Application No. 11/251,465

Filing Date: December 12, 2005

In re application of Farid Vaghefi et al.

June 5, 2008 Page: 3

9. (Original) An abuse-resistant composition according to claim 8 wherein the application of mechanical stress to said matrix increases the aqueous dissolution of active in said composition by less than about 10% of said pharmaceutically effective amount in the first hour, and does not substantially modify the dissolution rate of said composition thereafter.

- 10. (Original) An abuse-resistant composition according to claim 8 wherein said mechanical stress comprises crushing said composition.
- 11. (Original) An abuse-resistant controlled-release pharmaceutical composition according to claim 1 for administration to a subject in need thereof from once to four times a day.
- 12. (Withdrawn) A method for the preparation of an sustained release pharmaceutical composition having a reduced potential for abuse, comprising:
  - providing a pharmaceutically active compound capable of inducing in a subject a reaction that is physiologically or psychologically addictive if administered in an immediate release dosage form;
  - applying a pressure force to a mixture comprising particles of said compound and a water insoluble material thereby resulting in surface coated particles; and
  - incorporating said surface coated particles into a pharmaceutical composition that when subjected to stress does not increase substantially the immediate release of said compound in an aqueous environment.
- 13. (Withdrawn) A method according to claim 12 wherein said force is applied to a dispersion of said particles in a flowable medium comprising said material.
- 14. (Withdrawn) A method according to claim 13 wherein said force is an abrupt pressure force.
- 15. (Withdrawn) A method according to claim 13 wherein said force is an ultrasonic force.

In re application of Farid Vaghefi et al.

Application No. 11/251,465

Filing Date: December 12, 2005

Attorney Docket No. P26238-A USA

June 5, 2008 Page: 4

16. (Withdrawn) A method according to claim 13 wherein said force is piston generated shock

wave.

17. (Withdrawn) A method according to claim 13 wherein said particles are micronized.

18. (Withdrawn) A method according to claim 17 wherein said particles have a mean particle size

of less than about ten microns.

19. (Withdrawn) A method according to claim 13 wherein said material comprises a polymorphic

wax

20. (Withdrawn) A method according to claim 19 wherein said wax comprises a hydrogenated

vegetable wax, a tri-, di- or mono-glyceride, or a mixture thereof.

21. (Withdrawn) A method according to claim 20 wherein said material comprises a polymeric

material that is water insoluble, and erodable in the intestinal tract at pH greater than about 6.

22. (Withdrawn) A method according to claim 13 further comprising solidifying said dispersion

into microspheres.

23. (Withdrawn) A method according to claim 12 wherein the application of mechanical stress to

said composition modifies the aqueous dissolution of said compound by an increase of less than

about 15% of said pharmaceutically effective amount in the first hour, and does not

substantially modify the dissolution rate of said composition thereafter.

24. (Original) A dosage form according to claim 7 wherein said narcotic is selected from the group

consisting of fentanyl, sufentanil, carfentanil, lofentanil, alfentanil, hydromorphone, oxycodone,

hydroxycodone, propoxyphene, pentazocine, methadone, tilidine, butorphanol, buprenorphine,

levorphanol, codeine, oxymorphone, meperidine, dihydrocodeinone and cocaine.